K002784

SEP 2 0 2000

510(k) Summary:

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

This premarket notification has been submitted by Aloka Co., Ltd. and covers the Aloka UST-5280-5 diagnostic ultrasound transducer. The address is:

10 Fairfield Boulevard
Wallingford, CT 06492

The contact person is Christopher M. Bohl, Technical Product Manager.

The proprietary name is the Aloka UST-5280-5 diagnostic ultrasound transducer. The common name for this type of device is a diagnostic ultrasound transducer.

The item in this submission is covered under the following classification:

90 ITX - Transducer, Ultrasonic, Diagnostic

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The Aloka UST-5280-5 is substantially equivalent to the Aloka UST-5258 and UST-5228-5 diagnostic ultrasound transducers.

The Aloka UST-5280-5 functions in the same manner as other diagnostic ultrasound devices. High frequency sound waves are transmitted into the body by a piezo-electric transducer. In the body, differences in the acoustic impedance of different tissues reflect a certain amount of the ultrasound energy back to the transducer, where it is transmitted via the probe cable to the system console and processed into an image. The Aloka UST-5280-5 transducer can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka UST-5280-5, like other marketed diagnostic ultrasound transducers, is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka UST-5280-5 diagnostic ultrasound transducer is similar in technological characteristics to ultrasound transducers marketed by Aloka and others:

- The UST-5280-5 is indicated for the same diagnostic ultrasound applications as other products currently marketed by Aloka and others.
- The UST-5280-5 has the same gray-scale and Doppler abilities as other products currently offered by Aloka and others.
- The UST-5280-5 uses essentially the same technologies for imaging, Doppler functions and signal processing as other products currently marketed by Aloka and others.
- The UST-5280-5 has the same method of use as other products currently marketed by Aloka and others.

- The UST-5280-5 acoustic power output levels are below the maximum levels allowed by the FDA.
- The UST-5280-5 is subjected to the same Quality Assurance systems in development and production as other products currently marketed by Aloka.
- The patient contact materials used in the UST-5280-5 have been evaluated for safety via the same standards and methods as other products marketed by Aloka and others. These materials have been found to be safe for the intended uses. Test results can be found in Appendix 3.
- The UST-5280-5 complies with the same electrical and physical safety standards as other products currently marketed by Aloka and others.
- Aloka Co., Ltd. Certifies that the UST-5280-5 complies with NEMA-UD2 "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment", the AIUM 1998 "Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment", IEC60601-1-2, IEC60601-2-37, UL-544 and ISO10993. All testing is complete and the results meet the requirements of the standards above. Testing results for biocompatibility can be found in Appendix 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2000

Aloka Co., Ltd.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K002784
Aloka UST-5280-5
Regulatory Class: II
21 CFR §892.1570/Procode: 90 ITX
Dated: September 5, 2000
Received: September 6, 2000

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Aloka UST-5280-5 transducer intended for use with the Aloka SSD-5500 diagnostic ultrasound system as described in your premarket notification:

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.3
4.3.1

Diagnostic Ultrasound Indications for Use Form
UST-5280-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N	N	N	N		See Below	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002784